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23 **UNITED STATES DISTRICT COURT**

24 **SOUTHERN DISTRICT OF CALIFORNIA**

25 KFX MEDICAL CORP.

26 Case No. 3:11-CV-01698 DMS-BLM

27 Hon. Dana M. Sabraw

28 Plaintiff and Counterdefendant,

vs.

ARTHREX, INC.

Defendant and Counterclaimant.

**DEFENDANT ARTHREX, INC.’S
OPPOSITION TO PLAINTIFF’S
MOTION TO (A) DISMISS
DEFENDANT’S COUNTERCLAIM
FOR INEQUITABLE CONDUCT IN
CONNECTION WITH U.S. PATENTS
8,100,942 AND 8,109,969; (B) STRIKE
THE CORRESPONDING AFFIRMATIVE
DEFENSE; AND (C) EXTEND TIME TO
ANSWER REMAINING
COUNTERCLAIM ALLEGATIONS**

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1 **I. INTRODUCTION**

2 In its original complaint, plaintiff KFx Medical Corp. (“KFx”) asserted U.S. Patent No.
 3 7,585,311 (“the ‘311 patent”) against defendant Arthrex, Inc. (“Arthrex”). In its original answer and
 4 counterclaims, Arthrex alleged that KFx’s CEO, Mr. Tate Scott, committed inequitable conduct on
 5 the PTO by his failure to disclose -- both during prosecution and reexamination of the ‘311 patent --
 6 that he knew the work described in a prior art reference, known as the Millett article, had actually
 7 been performed by Dr. Millett prior to the earliest provisional application filing date of the ‘311
 8 patent (*i.e.*, prior to June 2, 2004).

9 This omission was highly material because, on its face, the Millett article was *not* obviously
 10 prior art to the application for the ‘311 patent – it has a publication date of October 2004, which is
 11 later than June 2, 2004. Thus, without the benefit of Mr. Scott’s withheld information, two separate
 12 Examiners (one during prosecution and one during reexamination) had no reason to apply the Millett
 13 article to reject the claims -- and indeed, they did not. Arthrex also alleged that Mr. Scott’s omission
 14 was highly material because the Millett article disclosed the exact same limitations the prosecution
 15 Examiner found missing in the two prior art references he *did* apply and that had both Examiners
 16 known when Dr. Millett actually performed his work (the information Mr. Scott failed to provide),
 17 they would not have allowed the claims in the ‘311 patent.

18 On April 3, 2012, KFx amended its complaint to assert two newly issued patents; U.S. Patent
 19 Nos. 8,100,942 (“the ‘942 patent”) and 8,109,969 (“the ‘969 patent”). In its answer to KFx’s
 20 amended complaint, Arthrex alleged three additional grounds for inequitable conduct regarding the
 21 newly asserted patents.

22 Arthrex’s first two grounds stem from Mr. Scott’s original failure to disclose the withheld
 23 information regarding the Millett article during prosecution and reexamination of the ‘311 patent. In
 24 short, and as explained in detail below, Arthrex’s first ground alleges that KFx’s prosecution counsel
 25

1 misled the Examiner during prosecution of the '942 and '969 patents into believing that Mr. Scott's
 2 withheld information was actually considered by another Examiner during reexamination of the '311
 3 patent, and thus, there was no reason for the Examiner to actually consider and apply that
 4 information to reject the claims of the '942 and '969 patents. Arthrex's second ground, as explained
 5 more fully below, alleges that KFx's counsel failed to disclose to the PTO the fact that the '969
 6 patent is only entitled to a priority date of June 1, 2005. The reason why this is important is because
 7 had the Examiner known that fact, he would have applied the Millett article itself (which is dated
 8 October 2004) as prior art to reject the claims even though he had not actually considered Mr.
 9 Scott's withheld information (since he thought another Examiner had already done so). Thus, he did
 10 not need to be aware of the withheld information (which KFx's counsel coaxed him into not
 11 reviewing) in order to apply the Millett article itself.
 12

13 Arthrex's third ground is independent of Mr. Scott's withheld information and instead deals
 14 with KFx's counsel's failure to disclose Arthrex's highly material invalidity contentions (from this
 15 case) to the PTO in connection with the '969 patent. In short, the reason why this amounts to
 16 inequitable conduct is because the contentions were highly material as they alleged anticipation of
 17 the claims, KFx's counsel knew they alleged anticipation, KFx's counsel had a continuing Rule 56
 18 obligation to disclose any information material to patentability yet failed to do so even though the
 19 PTO provided step-by-step instructions for having that material information actually considered.
 20

21 In its motion, KFx asserts that each of Arthrex's three separate grounds of inequitable
 22 conduct cannot support a claim of inequitable conduct as a matter of law. As explained below, KFx
 23 is wrong -- each of Arthrex's three grounds for inequitable conduct are legally supported and
 24 sufficiently pled.
 25

26 To make its "insufficient legal theory" arguments, KFx tells only half a story, essentially
 27 ignoring material facts included in Arthrex's Answer and Counterclaims (Ex. 1)--*material facts that*
 28

1 *must be accepted as true and construed in a light most favorable to Arthrex--and then attacks the*
 2 *legal theory based on KFx's incomplete version of the allegations. KFx Mem. at 9-11, 12-16, 18-19.*
 3 *When the allegations are considered in their entirety and in their proper context, as shown below,*
 4 *they are long-recognized as supporting claims of inequitable conduct.*

5 KFx also asserts that Arthrex insufficiently pled materiality and/or intent in connection with
 6 its three grounds of inequitable conduct. KFx Mem. at 11-12, 16-17, 18-20. The short answer is
 7 Arthrex's inequitable conduct allegations span ninety (90) paragraphs and more than seventeen (17)
 8 pages of its affirmative defenses and counterclaims. Ex. 1 at 6-16, 18-26. These allegations explain
 9 in painstaking detail not only the "who," "what," "where," "when," and "how" regarding each
 10 separate allegation, but they also allege detailed facts that more than meet the "reasonable inference"
 11 standard required to plead materiality and intent. But, to the extent there is any doubt regarding the
 12 sufficiency of Arthrex's extensive allegations as pleaded, Arthrex should be given leave to amend its
 13 Answer and Counterclaims to bring them into compliance.

14 Lastly, it is far too early in the case for the drastic result of dismissing one of Arthrex's
 15 affirmative defenses and counterclaims. At the very least, discovery should take its course before
 16 these defenses are stricken. KFx itself recognizes it is too early to move on Arthrex's inequitable
 17 conduct allegations regarding the '311 patent. As mentioned above, and described in detail below,
 18 Arthrex's first two grounds in connection with the '942 and '969 patents are inextricably connected
 19 to the facts of the '311 patent's inequitable conduct. Thus, it is also too early to move on Arthrex's
 20 new grounds of inequitable conduct regarding the '942 and '969 patents.

21 **II. LEGAL STANDARDS**

22 When making a determination under Fed. R. Civ. P. 12(b)(6), "[a]ll allegations of material
 23 fact must be taken as true and construed in the light most favorable to the non-moving party."

24 *Federation of African American Contractors v. City of Oakland*, 96 F.3d 1204, 1207 (9th Cir. 1996).

1 A claim of inequitable conduct has “facial plausibility” when facts are pled that “allow[] the court to
 2 draw the reasonable inference that” the alleged inequitable conduct occurred. *Iqbal*, 556 U.S. at 678.
 3 (citing *Twombly*, 550 U.S. at 556). “The plausibility standard is not akin to a ‘probability
 4 requirement.’” *Id.* In other words, to be sufficiently pled, one alleging inequitable conduct must
 5 merely “nudge[the inequitable conduct] claims . . . ‘across the line from conceivable to plausible.’”
 6 *Iqbal*, 556 U.S. at 680 (quoting *Twombly*, 550 U.S. at 570).

7 “The standard for deciding a motion to strike an affirmative defense as ‘insufficient’ is the
 8 same as for a motion to dismiss a complaint for failure to state a claim.” *U.S. S.E.C. v. Sachdeva*,
 9 No. 10-C-747, 2011 WL 933967, at *1 (E.D. Wis. Mar. 16, 2011) (citing *Renalds v. S.R.G. Rest.*
 10 *Grp*, 119 F. Supp. 2d 800, 802 (N.D. Ill. 2000)).

11 The Federal Circuit established the requirement for pleading inequitable conduct in *Exergen*
 12 *Corp. v. Wal-Mart Stores, Inc.*, 575 F.3d 1312, 1328 (Fed. Cir. 2009). “To plead the
 13 ‘circumstances’ of inequitable conduct with the requisite ‘particularity’ under Rule 9(b), the
 14 pleading must identify the specific who, what, when, where, and how of the material
 15 misrepresentation or omission committed before the PTO.” *Id.* at 1328. In addition, “although
 16 ‘knowledge’ and ‘intent’ may be averred generally, a pleading of inequitable conduct under Rule
 17 9(b) must include sufficient allegations of underlying facts from which a court may reasonably infer
 18 that a specific individual (1) knew of the withheld material information or of the falsity of the
 19 material misrepresentation, and (2) withheld or misrepresented this information with a specific intent
 20 to deceive the PTO.” *Id.* at 1328-29.

21 Further, although *Therasense, Inc. v. Becton, Dickinson & Co.*, 649 F.3d 1276, 1290 (Fed.
 22 Cir. 2011) (en banc) heightened the intent requirement for ultimately *proving* inequitable conduct
 23 after *Exergen*, the Federal Circuit has since affirmed *Exergen*’s requirement of a “reasonable
 24 inference” of intent at the pleading stage. *See Delano Farms Co. v. Cal. Table Grape Comm’n*, 655
 25

1 F.3d 1337, 1350 (Fed. Cir. 2011) (citing *Exergen*, 575 F.3d at 1318, 1330; citing generally
 2 *Therasense*) (emphasis added). *See also Sanders v. The Mosaic Co.*, 418 Fed. Appx. 914, 919 (Fed.
 3 Cir. 2011) (“*At the pleading stage* the proponent of the inequitable conduct theory *need only plead*
 4 *facts supporting a reasonable inference* that a specific individual knew of the misrepresentation and
 5 had the specific intent to deceive the PTO.” (citing *Exergen*, 575 F.3d at 1328–29) (emphasis
 6 added)); *Bayer Cropscience AG v. Dow Agrosciences LLC*, 2012 WL 1253047 *4 (D. Del. Apr. 12,
 7 2012) (“The Court will not determine whether this is the single most reasonable inference to be
 8 drawn from the well pleaded facts.”); *Sloan Valve Co. v. Zurn Industries, Inc.*, 2012 WL 1108129,
 9 *5, n.5 (N.D. Ill. Apr. 2, 2012); *Wyeth Holdings Corp. v. Sandoz, Inc.*, 2012 WL 600715, *7 (D. Del.
 10 Feb. 3, 2012). “A reasonable inference is one that is plausible and that flows logically from the facts
 11 alleged, including any objective indications of candor and good faith.” *Exergen*, 575 F.3d at 1329 n.
 12 5.

13
 14 This lower pleading standard is significant because, as the Federal Circuit noted, especially at
 15 the pleading stage, “direct evidence of deceptive intent is rare” so “a district court may infer intent
 16 from indirect and circumstantial evidence.” *Therasense*, 649 F.3d at 1290.

17
III. ARGUMENT

18 As described above, Arthrex alleges three new separate grounds of inequitable conduct in
 19 connection with the ‘942 and ‘969 patents. Below, each separate ground is described in detail. And
 20 for each separate ground, we show that it is both legally supported as a claim of inequitable conduct
 21 and that it was sufficiently pled.

22
**A. Arthrex’s Allegations That Mr. Melnick Misled the Examiner Into Believing the
 23 Scott Statement Had Already Been Considered By Another Examiner Are
 24 Legally Sufficient and Sufficiently Pled**

25
1. This Ground of Inequitable Conduct is Legally Supported

26 This first ground of inequitable conduct has its roots in Mr. Scott’s (KFX’s CEO), failure to

1 disclose to two different Examiners when he first became aware that Dr. Millett actually performed
 2 the work described in his article prior to when KFx filed any of its patent applications. As shown
 3 below, dating back to the '311 patent prosecution, there has been a pattern of deceptive behavior all
 4 designed to prevent the Examiner from actually considering the work described in the Millett article.
 5 That behavior continued into prosecution of the '942 and '969 patents where KFx's counsel made
 6 affirmatively misleading statements intended to have the Examiner believe that the information had
 7 already been considered by another Examiner, so there was no need for him to do so.
 8

9 We begin with the prosecution of the '311 patent, during which KFx's prosecution counsel,
 10 Mr. Melnick, filed an Information Disclosure Statement ("IDS") citing the Millett article.¹ The
 11 Millett article, on its face, has a publication date of October 2004. (Ex. 1 at ¶¶ 83, 85²). The '311
 12 patent claims priority on its face to three provisional applications, the earliest of which is dated June
 13 2, 2004 (¶ 87). Since the earliest priority dates on the application were earlier than the publication
 14 date on the Millett article, the Examiner had no reason to believe the Millett article was prior art, and
 15 therefore, did not apply it in rejecting the claims. (¶ 89).

16 Also during prosecution of the '311 patent, KFx's CEO, Mr. Tate Scott, learned that Dr.
 17 Millett actually performed the work described in the Millett article prior to when any of the
 18 provisional applications were filed and at least as early as March 2003. Thus, Mr. Scott knew the
 19 work described in the Millett article was prior art to his application ("the Withheld Information") yet
 20 he failed to disclose this material information to the Examiner during prosecution of the '311 patent.
 21 (¶¶ 96-100, 109, 117)). The reason why the Withheld Information is material to patentability is
 22

23 ¹ "Mattress Double Anchor Footprint Repair: A Novel Arthroscopic Rotator Cuff Repair
 24 Technique;" *Arthroscopy: The Journal of Arthroscopic and Related Surgery*, Vol. 20, No. 8
 25 (October), 2004: pp. 875-879.

26 ² All cites to paragraph numbers refer to the specific numbered paragraphs included in
 27 Arthrex's Answer to Plaintiff KFx Medical Corp.'s First Amended Complaint for Patent
 Infringement and Counterclaims. Ex. 1.

1 because it disclosed *the same subject matter the Examiner stated was missing from the two main*
 2 *references he did specifically apply in an Office Action:* the Thal and Jobe references. (¶148). Mr.
 3 Scott also knew the Withheld Information was material. (¶ 113). And had the Examiner known of
 4 the Withheld Information, he would have rejected the pending claims because it would have been
 5 obvious to combine any missing limitations from Thal and Jobe with the Withheld Information. (¶
 6 115). Instead, Mr. Scott said nothing and the '311 patent issued. (¶ 90).

7 Mr. Scott had yet another opportunity to disclose the Withheld Information to the PTO
 8 during reexamination of the '311 patent, but he failed to do so again. (¶¶ 95-109, 118). During
 9 reexamination of the '311 patent, Mr. Melnick filed an IDS including a sworn statement by Mr.
 10 Scott stating that he knew the work performed in the Millett article had been performed in the two
 11 years preceding publication of the article ("the Scott Statement"). (¶¶ 95-98, 100). But because KFx
 12 filed its IDS too late in the process, the PTO refused to consider it. (¶¶ 103, 104).

13 Mr. Melnick himself acknowledged that the Scott Statement was material to patentability by
 14 telling the Examiner that "consideration of this information by the Examiner is appropriate." (¶¶
 15 105-107). The PTO refused to consider the IDS, stating that "there is no showing as to when patent
 16 owner first became aware of the existence of the items of information now being submitted, and no
 17 explanation as to why the information could not have been submitted earlier." (¶ 108). Thus, Mr.
 18 Scott failed twice (once during prosecution of the '311 patent, and again during reexamination of the
 19 '311 patent) to disclose the Withheld Information and when he first learned of the Withheld
 20 Information. (¶¶ 117-118).

21 The result was that, at the end of the reexamination process for the '311 patent, the PTO *still*
 22 had not actually considered and applied the work described in the Millett article even though Mr.
 23 Scott and Mr. Melnick had, at that point, known for years that the Withheld Information was
 24 material to patentability. But KFx's deception regarding the Withheld Information did not end there.

1 When it came time to prosecute the ‘942 and ‘969 patents, as shown below, Mr. Melnick
 2 actually went out of his way to make misleading statements designed to take the Examiner off of the
 3 trail of the highly material Withheld Information. Specifically, during prosecution of the ‘942 and
 4 ‘969 patents, Mr. Melnick filed an IDS stating that Mr. Scott’s statement was “submitted in the Re-
 5 examination,” *but he failed to inform the Examiner that the PTO refused to consider Mr. Scott’s*
 6 *statement because KFx filed it too late.* (¶¶ 123, 128, 129). This statement was *designed to mislead*
 7 *the Examiner into believing Mr. Scott’s statement had already been considered* by another Examiner
 8 at the PTO and that there was no need for this Examiner to review it again.

10 Making matters worse, Mr. Melnick then requested an interview with the Examiner to
 11 ostensibly discuss the most relevant prior art references. (¶¶131-132). But Mr. Melnick did not
 12 bring up the Scott Statement or the Withheld Information during that interview *even though he knew*
 13 *the PTO had not yet considered or applied that material information.* Rather, Mr. Melnick chose to
 14 discuss the same two prior art references (Thal and Jobe) that had already been overcome during
 15 prosecution of the ‘311 patent, which had claims with limitations similar to those also included in
 16 the ‘942 and ‘969 patents. (¶¶ 133-136).

18 Due to Mr. Melnick’s misleading statement and his attempt during the interview to divert the
 19 Examiner’s attention *away* from the highly material Withheld Information, in favor of discussing the
 20 much less material Thal and Jobe references, the PTO once again did not specifically apply the work
 21 described in the Millett article to reject the claims. (¶ 140). The fact that the Examiner did not
 22 actually consider the Scott Statement (even though he checked it off on the IDS) is obvious since the
 23 Examiner pointed to the exact same “reasons for allowance” he pointed to in allowing the ‘311
 24 patent – *and those reasons specifically identify limitations disclosed in the work described by the*
 25 *Millett article, as acknowledged by Mr. Scott himself.* (¶¶ 112-113, 146-149, 153).

27 The Federal Circuit has found inequitable conduct where, in situations just like this one, the
 28

1 applicant has made misleading statements about a disclosed reference that “left the examiner with
 2 the impression that the examiner did not need to conduct any further investigation” regarding the
 3 disclosed reference. *eSpeed, Inc. v. BrokerTec USA, L.L.C.*, 480 F.3d 1129, 1138 (Fed. Cir. 2007).
 4 Mr. Melnick’s misleading statement regarding the Scott Statement did just that – left the Examiner
 5 with the impression he did not need to review it again. But as we know, that was not the case.
 6

7 Throughout the entire history described above, including the prosecution and reexamination
 8 of the ‘311 patent, and the prosecution of the ‘942 and ‘969 patents, both Mr. Scott and Mr. Melnick
 9 worked to ensure that neither Examiner (the prosecution Examiner, nor the reexamination Examiner)
 10 would actually consider and apply the Withheld Information, and thereby, the work described in the
 11 Millett article. Their motives and intent to deceive the PTO are clear. (¶ 153). They knew that the
 12 Millett article disclosed the very same limitations the PTO found missing in Thal and Jobe. And had
 13 the Examiner actually paid attention to the Scott Statement, he would have applied the work
 14 described in the Millett article to reject the claims. (¶ 143).
 15

16 Patterns of deceit, such as those alleged in this case, are routinely found sufficient to support
 17 a claim of inequitable conduct. *See, e.g., Paragon Podiatry Laboratory, Inc. v. KLM Laboratories,*
 18 *Inc.*, 984 F.2d 1182, 1194 (Fed. Cir. 1993) (“The prosecution of the patent application in this case,
 19 viewed in its entirety, demonstrates an overriding pattern of misconduct sufficient to support the
 20 district court’s finding of culpable intent.”); *W.L. Gore & Associates, Inc. v. Medtronic, Inc.*, 2012
 21 WL 368272 at *4 (E.D. Va. Feb. 3, 2012) (refusing to dismiss or strike an inequitable conduct
 22 pleading where the defendant alleged intentional mischaracterization of material information and “a
 23 pattern of deception”); *Southco, Inc. v. Penn Engineering & Mfg. Corp.*, 768 F. Supp. 2d 715 (D.
 24 Del. 2011) (denying motions to dismiss and strike inequitable conduct defenses because the
 25 plaintiff’s “alleged misrepresentations affected the Examiner’s evaluation of the patents-in-suit”);
 26 *Onstar, LLC v. Micral, Inc.*, 2010 WL 1433431, at *11 (N.D. Ohio Apr. 7, 2010) (finding
 27

1 inequitable conduct where the “inequitable conduct was not limited to a single instance and
 2 represents a pattern of intentional deception”); *DaimlerChrysler AG v. Feuling Advanced*
 3 *Technologies, Inc.*, 276 F. Supp. 2d 1054 (S.D. Cal. 2003).

4 KFx ignores most of the above-described facts and instead argues that there can be no
 5 inequitable conduct as long as a reference was submitted to the Examiner in an IDS and the
 6 Examiner initialed the reference. KFx Memorandum (“KFx Mem.”) at 9-10. KFx also argues there
 7 can be no inequitable conduct where the applicant failed to specifically point out the relevance of a
 8 reference. KFx Mem. at 10-11. Both of these arguments miss the point. Arthrex is not alleging that
 9 Mr. Melnick failed to disclose the Scott Statement during prosecution of the ‘942 and ‘969 patents.
 10 Arthrex is also not merely alleging that Mr. Melnick should have pointed out the Scott Statement to
 11 the Examiner during prosecution. KFx Mem. at 9-11.

12 Rather, as explained above, Arthrex is alleging that Mr. Melnick went out of his way to point
 13 out the Scott Statement and then mislead the Examiner into believing another Examiner (the one
 14 handling the reexamination) actually reviewed and considered the Scott Statement and that the
 15 Examiner therefore did not need to. Mr. Melnick’s telling the Examiner that the Scott Statement was
 16 “submitted in the Reexamination” was a “classic example of a half-truth.” *Paragon Podiatry*
 17 *Laboratory, Inc. v. KLM Laboratories, Inc.*, 984 F.2d 1182, 1192 (Fed. Cir. 1993) (emphasis added).

18 And to the extent KFx argues for some sort of “per se” rule that there can be no inequitable
 19 conduct regarding a reference that was submitted and initialed by the Examiner (KFx Mem. at 9-10),
 20 that is simply incorrect. What *does* matter is what the applicant says about a reference that has been
 21 submitted. If the applicant makes misleading statements about a reference that was submitted and
 22 initialed by the Examiner, such as in this case, there most certainly can be a finding of inequitable
 23 conduct. *See, e.g., eSpeed*, 480 F.3d at 1138 (finding inequitable conduct where applicant made
 24 misleading statements about prior art that was considered by the Examiner); *W.L. Gore &*
 25 *10*
 26 *ARTHREX’S OPPOSITION TO KFX’S MOTION TO DISMISS DEFENDANT’S COUNTERCLAIM FOR*
 27 *INEQUITABLE CONDUCT IN CONNECTION WITH U.S. PATENTS 8,100,942 AND 8,109,969 AND*
 28 *STRIKE THE CORRESPONDING AFFIRMATIVE DEFENSE*

1 Associates, Inc., 2012 WL 368272 at *4 (court did not dismiss inequitable conduct defense alleging
 2 misleading statements regarding prior art references submitted in an IDS and initialed by the
 3 Examiner).

4 The cases relied upon by KFx involve very different facts than those involved here. For
 5 example, KFx relies upon *Scripps Clinic & Research Found. v. Genentech, Inc.*, 927 F.2d 1565
 6 (Fed. Cir. 1991), for the proposition that a reference cannot be “withheld” from the examiner if it
 7 was before the Examiner. KFx Mem. at 9-10. It is nothing more than a garden-variety case where
 8 the Federal Circuit held that you cannot argue inequitable conduct based on failure to disclose if the
 9 reference was before the Examiner. But *Scripps Clinic* does not deal with facts remotely like those
 10 here where inequitable conduct is based on actions by KFx which affirmatively misled the Examiner
 11 regarding those materials in an attempt to ensure that Mr. Scott’s statement and the work described
 12 in the Millett article would not be applied in rejecting the claims.

13
 14 KFx also relies upon *Fiskars, Inc. v. Hunt Mfg. Co.*, 221 F.3d 1318 (Fed. Cir. 2000) for the
 15 proposition that there cannot be inequitable conduct where the applicant failed to “stress the
 16 relevance” of certain references to the Examiner, even if those references were submitted but not
 17 considered by the Examiner. KFx Mem. at 10. Again, this misses the point as Arthrex alleges much
 18 more than this. Not only did Mr. Melnick fail to point out the relevance of Mr. Scott’s statement,
 19 but he created the false impression that another Examiner at the PTO had already considered it
 20 through a series of misleading acts.

21
 22 **2. Arthrex Has Alleged Facts Supporting an Intent to Deceive the PTO
 23 With Regard to This Ground of Inequitable Conduct**

24
 25 KFx asserts that Arthrex “does not allege specific facts demonstrating an intent to deceive on
 26 the part of Melnick” and that Arthrex “only generally avers an intent to deceive, stating only that
 27 Melnick’s actions were ‘done knowingly, deliberately, and with the specific intent to deceive the

1 PTO as to which references were the most material.” KFx Mem. at 11. In making this assertion,
 2 KFx points to a single paragraph of Arthrex’s 90-paragraph inequitable conduct allegations and
 3 ignores the rest.

4 The Federal Circuit made clear that although *Therasense* heightened the intent requirement
 5 for ultimately *proving* inequitable conduct after *Exergen*, only a “reasonable inference” of intent is
 6 required at the pleading stage. *Delano Farms Co.*, 655 F.3d at 1350; *Sanders*, 418 Fed. Appx. at
 7 919. “A reasonable inference is one that is plausible and that flows logically from the facts alleged.”
 8 *Exergen*, 575 F.3d at 1329 n.5. This is important because, as the Federal Circuit noted, especially at
 9 the pleading stage “direct evidence of deceptive intent is rare,” so “a district court may infer intent
 10 from indirect and circumstantial evidence.” *Therasense*, 649 F.3d at 1290.

12 Contrary to KFx’s assertion, Arthrex alleged much more than the one paragraph to which
 13 KFx points in its motion. Arthrex established a long-term pattern of deceit dating back to the
 14 prosecution of the ‘311 patent, where Mr. Scott failed to disclose Dr. Millett’s prior work. *Supra* at
 15 6-7. It then continued through reexamination of the ‘311 patent where both Mr. Scott and Mr.
 16 Melnick again failed to disclose the same information. *Supra* at 7. It still continued into prosecution
 17 of the ‘942 and ‘969 patents where Mr. Melnick, by his acts, misled the Examiner into believing the
 18 Scott Statement had already been considered. *Supra* at 8. As described above, throughout that
 19 entire time, Mr. Scott and Mr. Melnick worked to prevent the PTO from actually considering the
 20 Scott Statement and the work described in the Millett article. *Supra* at 8.

22 Courts have routinely found a reasonable inference of intent when such patterns of deceit are
 23 alleged. *Paragon Podiatry Laboratory, Inc. v. KLM Laboratories, Inc.*, 984 F.2d 1182, 1193 (Fed.
 24 Cir. 1193) (“The prosecution of the patent application in this case, viewed in its entirety,
 25 demonstrates an overriding pattern of misconduct sufficient to support the district court’s finding of
 26 culpable intent.”); *Onstar, LLC v. Micral, Inc.*, 2010 WL 1433431, at *6-8 (N.D. Ohio Apr. 7, 2010).

1 Court have also found a reasonable inference of intent to deceive where, as here, the applicant has
 2 affirmatively misled the Examiner regarding information material to patentability. *Paragon*
 3 *Podiatry Laboratory, Inc.*, 984 F.2d at 1191.

4 **B. Arthrex's Allegations Regarding KFx's Failure to Disclose the Actual Priority
 5 Date of the '969 Patent Are Legally Sufficient and Sufficiently Pled**

6 **1. This Ground of Inequitable Conduct is Legally Supported**

7 As described above, Mr. Melnick's statement to the Examiner that the Scott Statement was
 8 "submitted in the Reexamination" of the '311 patent misled the Examiner into believing that another
 9 Examiner had already considered the Scott Statement, and therefore, there was no reason for him to
 10 review it. *Supra* at 7. And, in fact, there is no reason to believe the Examiner actually reviewed the
 11 Scott Statement, and every reason to believe he did not. *Supra* at 6-8.

12 But even though the Examiner did not review the Scott Statement, KFx had another
 13 opportunity to make sure Millett was considered, and it took steps to ensure that did not happen.
 14 The Examiner still would have applied the Millett article in rejecting the claims *if he had known the*
 15 *Millett article was prior art to the '969 patent*. But, as described below, Mr. Melnick never told the
 16 Examiner the correct priority date of the '969 patent, and thus, the Examiner never knew the Millett
 17 article was prior art to the '969 patent.

18 As Arthrex alleged in its Answer, the '622 application, which issued as the '969 patent,
 19 claims priority back to three provisional applications, one of which was filed as early as June 2,
 20 2004. (¶ 120). The Millett article was published in October 2004; thus, the Examiner had no reason
 21 to believe it was prior art to the '622 application. (¶¶ 142, 142). At the time, however, Mr. Melnick
 22 knew, but did not inform the Examiner, that the '622 application is only entitled to a priority date of
 23 June 1, 2005, thus making the Millett article prior art to the '622 application. (¶ 141). As explained
 24 above, there is no question that the Millett article is material because it discloses the same exact
 25
 26
 27

1 limitations the Examiner identified as missing from the Thal and Jobe references he *did* consider.
 2 (¶¶ 146-147). If the Examiner knew that the Millett article was prior art to the ‘622 application, he
 3 would have applied the Millett article in rejecting the claims. (¶ 143).

4 When deciding which cited references are prior art to an application, the Manual of Patent
 5 Examining Procedure (MPEP) section 706.02 instructs the Examiner to compare the date on a prior
 6 art reference to the “effective filing date” of the application, and that the effective filing date of an
 7 application “is the filing date of the provisional application.” MPEP § 706.02.³ Since Mr. Melnick
 8 never told the Examiner that the priority date of June 2, 2004 was incorrect, the Examiner had every
 9 reason to believe the priority claim was correct. Mr. Melnick’s failure to disclose the correct priority
 10 date resulted in the Examiner not applying the Millett article to reject the claims.

11 In *Li Second Family Ltd. Partnership v. Toshiba Corp.*, 231 F.3d 1373 (Fed. Cir. 2000), the
 12 Federal Circuit found inequitable conduct where, as in this case, the applicant failed to disclose the
 13 actual priority date to which his application was entitled and that failure resulted in the elimination
 14 of what would otherwise have been a material prior art reference. *Id.* at 1380. In that case, the
 15 Federal Circuit found the omitted priority date information “highly material.” *Id.*

16 KFX argues that the failure to disclose the priority date of the ‘622 application is not material
 17 since “the Millett work described in the Scott Statement predicated all KFX applications.” KFX Mem.
 18 at 12-13. Essentially, KFX argues that the Millett article would have been cumulative of *the work*
 19 *described in* the Millett article, which, according to KFX, the Examiner already considered because
 20 he had already considered the Scott Statement.

21 But as Arthrex explained above, the Examiner *did not* consider the Scott Statement because

22 ³ KFX asserts that Arthrex cannot be certain the Examiner relied on the September 17, 2004
 23 provisional date rather than one of the other two provisional dates (i.e., June 2, 2004 or December 7,
 24 2004). KFX Mem. at 16. As mentioned above, however, the most likely date the Examiner relied
 25 upon was June 2, 2004, pursuant to MPEP section 706.02.

1 Mr. Melnick misled him into believing that another Examiner had already considered it. *Supra* at 7.
 2 These allegations as pled must be accepted as true for purposes of this motion. *Federation of*
 3 *African American Contractors*, 96 F.3d at 1207. And accepting as true the fact that the Examiner
 4 *did not* consider the Scott Statement, the priority date of the '622 application becomes highly
 5 material because had the Examiner known of the actual priority date, he would have instantly
 6 noticed it is later than the date on the Millett article. This failure to disclose was "highly material"
 7 since it eliminated the Millett article as a reference. *Li Second Family Ltd. Partnership*, 231 F.3d at
 8 1380.

10 KFx's reliance upon *Purdue Pharma v. Boehringer Ingelheim GMBH*, 237 F.3d 1359 (Fed. Cir
 11 2000), is misplaced. First, it applies a standard not applicable to this case. The inquiry in that case
 12 dealt with whether the inequitable conduct had "substantial merit" for purposes of granting a
 13 preliminary injunction, and not whether a reasonable inference of inequitable conduct was
 14 sufficiently plead. *Id.* at 1366-67. Further, in that case, unlike here, *the Examiner acknowledged*
 15 *that the application may have a later priority date. See, id.* at 1367 ("In fact, the examiner himself
 16 recognized that the claims of the '912 patent were based on 'additional disclosure not presented in
 17 the ['331 parent],' which suggests that the examiner did not assume that the claims are entitled to the
 18 priority date of the '331 parent.'") (alterations in original). The facts here are much different. Here,
 19 the Examiner did not have any reason to believe the claims of the '622 application were not entitled
 20 to the priority date of the provisional application. And Mr. Melnick's failure to disclose the actual
 21 priority date was "highly material." *Li Second Family Ltd. Partnership*, 231 F.3d at 1380.

24 **2. Arthrex Has Alleged Facts Supporting an Intent to Deceive the PTO
 25 With Regard to This Ground of Inequitable Conduct**

26 As explained above, Mr. Scott's misconduct dates back to the '311 patent where he failed to
 27 disclose the fact that the work performed in the Millet article was prior art to his application. Mr.

1 Melnick and Mr. Scott also made certain the PTO would not consider the Scott Statement during the
 2 '311 patent reexamination by waiting too long to file it in an IDS. Then during prosecution of the
 3 '622 application, Mr. Melnick misled the Examiner into believing the Scott Statement had already
 4 been considered by another Examiner during reexamination, so he did not apply it to reject the
 5 claims, as is obvious by his statement of reasons for allowance. Even though Mr. Melnick still had a
 6 last opportunity to have the Examiner actually consider the Millett article, he made certain the
 7 Examiner did not have the information necessary for him to make the determination by failing to
 8 disclose the actual priority date for the '622 application.

9
 10 Courts have found culpable intent, and inequitable conduct, when there is a pattern of alleged
 11 misconduct spanning *only a single* prosecution. *W.L. Gore & Associates, Inc.*, 2012 WL 368272 at
 12 *4. But the facts alleged in this case are much more egregious. Here, Arthrex alleges that the
 13 pattern of misconduct spans not just one prosecution, but *two prosecutions and a reexamination*.
 14 Since the Federal Circuit has found intent based on facts not quite as egregious as those alleged, and
 15 since the standard of pleading intent is lower than its actual burden of proof, there is no doubt that
 16 Arthrex more than meets the "reasonable inference" pleading standard.

17
 18 KFx asserts there is no reasonable inference of intent to deceive because Mr. Melnick did not
 19 commit inequitable conduct merely by claiming priority to an earlier patent. KFx Mem. at 17. But
 20 as explained above, when the failure to disclose the priority date results in the elimination of an
 21 otherwise material prior art reference, the Federal Circuit has held otherwise. *Li Second Family Ltd.*
 22 *Partnership*, 231 F.3d at 1380.

23
 24 KFx also asserts there is no reasonable inference of intent to deceive since the PTO rules
 25 contemplate that the inclusion of a priority date does not necessarily indicate that the claims are
 26 entitled to the benefit of the earlier date. KFx Mem. at 17. KFx simply asserts a truism that not all
 27 claims of a patent will be entitled to the earliest priority date on the application. Of course this is
 28

1 correct (as we see first hand with the ‘622 application), but it misses the point. MPEP section
 2 706.02 instructs the Examiner that he is to consider the date of the provisional application as the
 3 effective filing date of the application. Where, as here, the Examiner is not told that the claims are
 4 not entitled to that provisional filing date, the Examiner will be relying on an incorrect date. And the
 5 reason why it matters in this case is because Mr. Melnick’s silence eliminated a material prior art
 6 reference.
 7

8 Lastly, KFx again relies on its submission of the Scott Statement as evidence that it did not
 9 intend to deceive the PTO. KFx Mem. at 17. But as explained above, Arthrex’s allegation that the
 10 Examiner did not consider the Scott Statement due to Mr. Melnick’s misleading statements, must be
 11 taken as true and correct. Thus, KFx cannot rely on the Examiner having considered the Scott
 12 Statement.
 13

**C. Arthrex’s Allegations Regarding KFx’s Failure to Have Arthrex’s Invalidity
 Contentions Considered By the PTO Are Legally Sufficient and Sufficiently Pled**

14 This ground of inequitable conduct has to do with Mr. Melnick’s failure to have Arthrex’s
 15 invalidity contentions actually considered by the PTO during prosecution of the ‘622 application (the
 16 ‘969 patent). Arthrex served its invalidity contentions on KFx in connection with this litigation on
 17 January 30, 2012. (¶ 155). As of that date, the ‘622 application was allowed and the issue fee was
 18 paid, however the ‘622 application *had not yet issued* as the ‘969 patent. (¶ 154).
 19

20 At that time, Mr. Melnick had a Rule 56 continuing duty of candor and good faith to disclose
 21 all material information to the PTO. (¶ 79). Mr. Melnick knew that Arthrex’s invalidity contentions
 22 were material to patentability since Arthrex alleged that the contentions included anticipatory
 23 references and other invalidity contentions not yet considered by the PTO. (¶¶ 156-57). Despite
 24 this, Mr. Melnick chose not to submit the invalidity contentions in a way where the Examiner would
 25 actually consider them. Instead, he chose to merely have the contentions placed in the file where he
 26
 27

1 knew they would never be considered. (¶ 160).

2 Mr. Melnick took the “place the reference in the file” route even though the PTO prescribes a
 3 process for having a reference considered in exactly this same situation. As the PTO describes, Mr.
 4 Melnick could have simply withdrew the ‘622 application from issue and filed a request for
 5 continued examination (RCE), pursuant to MPEP § 609.04(b). (¶ 162, 163). Instead, Mr. Melnick
 6 was in a rush to have the ‘969 patent issue so that KFx could assert it against Arthrex in this case
 7 without risk of having the claims rejected due to the invalidity contentions. In light of these facts,
 8 Arthrex alleged that Mr. Melnick’s failure to disclose the invalidity contentions was done
 9 knowingly, deliberately and with the specific intent to deceive the PTO. (¶ 168).

10 Courts have recently found inequitable conduct based on allegations, such as these, where the
 11 applicant failed to comply with its Rule 56 obligation by failing to disclose material prior art. *See*,
 12 *e.g.*, *Apotex Inc. v. Cephalon, Inc.*, 2011 WL 6090696, at * 26 (E.D. Pa. Nov. 7, 2011) (finding
 13 applicants failure to disclose material prior art to the PTO violated applicant’s rule 56 obligations,
 14 and was therefore inequitable conduct).

15 KFx does not deny Mr. Melnick had a continuing Rule 56 obligation to disclose all material
 16 information to the Examiner at that time (after the issue fee was paid but prior to issuance). Nor can
 17 it. The law is clear that the Rule 56 obligation is ongoing until the day the patent issues. *Apotex*
 18 *Inc.*, 2011 WL 6090696 at * 26 (“The duty of disclosure continues from the date of filing to the date
 19 of issuance.”). Instead, KFx argues that “no material information has been alleged to have been
 20 withheld.” KFx Mem. at 18-19. That allegation is clearly wrong. As demonstrated above,
 21 Arthrex’s Answer correctly alleged that the withheld invalidity contentions were “but for” material
 22 since they included anticipatory references and other invalidity contentions not yet considered by the
 23 PTO. *Supra* at 17.

24 KFx next argues that Arthrex’s allegations regarding intent are insufficient, and in doing so,
 25

1 attempts to make it appear as if Arthrex is basing “intent” merely on Mr. Melnick’s incorrect
 2 statement that he was submitting the invalidity contentions “for consideration” when he never
 3 actually did so. KFx Mem. at 19-20. Notably, KFx never denies Mr. Melnick used these words, but
 4 instead argues this alone cannot be the basis for inequitable conduct. But Arthrex’s basis for intent
 5 goes far beyond this. Mr. Melnick’s misleading and inappropriate choice of words are merely a
 6 symptom of a much greater problem – he knew that the invalidity contentions were material, he
 7 knew he had an ongoing Rule 56 obligation to disclose them, yet he deliberately chose not to do so
 8 when there was a process for him to have the materials considered.

10 Recently, this Court found intent to deceive on facts very similar to those here. In *American*
 11 *Calcar, Inc. v. American Honda Motor Co., Inc.*, 2012 WL 1328640, at *9-11 (S.D. Cal. April 17,
 12 2012), this Court found intent to deceive based on circumstantial evidence that the applicant knew
 13 the prior art was material and made a deliberate decision to withhold the prior art from the PTO.
 14 The Federal Circuit also found intent to deceive where, as here, an applicant failed to disclose a
 15 reference he knew to be material. *See e.g., Cargill, Inc. v. Canbra Foods, Ltd.*, 476 F.3d 1359,
 16 1366-67 (Fed. Cir. 2007) (finding intent to deceive based on consideration of several factors
 17 including: applicant should have known of the materiality of the prior art, applicant’s motives for
 18 obtaining the patent, and the high degree of materiality of the prior art).

19 KFx also seems to present some sort of policy argument that it would be an “unworkable
 20 scenario” to require an applicant to withdraw an application from issue when the applicant learns of
 21 material information not yet considered by the PTO. KFx Mem. at 18. But this ignores the fact that
 22 the MPEP *already requires such actions by the applicant under Rule 56*. And it ignores that the
 23 PTO has already considered this as being a “*workable*” scenario inasmuch as it provides a road map
 24 for doing exactly that in MPEP § 609.04(b). There is nothing to KFx’s argument.

1 **D. At the Very Least, Arthrex *Should* Be Given Leave to Amend**

2 KFX's sole basis for asserting that Arthrex should not be given an opportunity to amend its
 3 allegations is because its allegations "are simply insufficient as a matter of law to set forth any viable
 4 claim of inequitable conduct." KFX Mem. at 20. But as demonstrated above, Arthrex's allegations
 5 are legally supported. Thus, KFX's argument should be rejected.

6 But to the extent the Court disagrees that Arthrex's allegations are legally supported,
 7 amendment rather than dismissal is the appropriate remedy. The Ninth Circuit has advised against
 8 dismissal without leave to amend stating that "[d]ismissal without leave to amend is improper unless
 9 it is clear . . . that the [pleading] could not be saved by any amendment." *Polich v. Burlington*
 10 *Northern, Inc.*, 942 F.2d 1467, 1472 (9th Cir. 1991). As shown above, even in the unlikely event
 11 that Arthrex's extensive pleadings are found to be insufficient, Arthrex has demonstrated that it can
 12 amend its Answer and supplement its allegations if necessary. Thus, since any alleged deficiencies
 13 in Arthrex's pleadings could "be saved by any amendment," at the very least, Arthrex should be
 14 given an opportunity to amend.

15 **E. Dismissal of Arthrex's Allegations Regarding the Scott Statement and the '622**
 16 **Application Priority Date is Premature Since Those Allegations Are Tied to**
 17 **KFX's Inequitable Conduct Regarding the '311 Patent**

18 KFX did not move to dismiss or strike Arthrex's allegations of inequitable conduct regarding
 19 the '311 patent because, according to KFX, "that defense is more appropriately resolved by
 20 considering evidence outside the pleadings and will therefore be the subject of a summary judgment
 21 motion." KFX Mem. at 1, n.1. As explained above, Arthrex's allegations that Mr. Melnick misled
 22 the Examiner regarding the Scott Statement (*supra* at 5-9, 12) and that he failed to disclose the
 23 highly material priority date for the '622 application (*supra* at 13-17) are inextricably connected to
 24 KFX's allegations regarding the '311 patent. *Supra* at 3, 5-9, 12. KFX provides no justification to
 25 artificially separate out one portion of the single timeline alleged by Arthrex, save for its argument
 26
 27

1 that Arthrex's allegations are not legally sufficient. KFx Mem. at 20. But as shown above, that is
2 incorrect.

3 Because all of these allegations are inter-related, the parties should be permitted to take
4 discovery on all of these issues and then, if appropriate, move for summary judgment, as suggested
5 by KFx. Fact discovery in this case closes on December 21, 2012. Until then, both parties should be
6 given an opportunity to conduct discovery on these issues as appropriate. It is simply too early to
7 dismiss the allegations at this early stage. *See, e.g., Barnes & Noble, Inc. v. LSI Corp.*, 2012 WL
8 359713, at *15 (N.D. Cal. Feb. 2, 2012) ("Given the parties' factual dispute . . . striking this defense
9 is premature."); *Blue Nile, Inc. v. Ice.com, Inc.*, 478 F. Supp. 2d 1240, 1245-46 (W.D. Wash. 2007)
10 (denying motion to dismiss "at this early stage of the litigation" after noting benefit of making
11 decision at later stage with "developed factual background on summary judgment").

12 Lastly, although KFx did not raise this issue during the parties' meet and confer, Arthrex
13 consents to KFx's request to file a single answer to Arthrex's counterclaims following a decision on
14 its motion.

15 **IV. CONCLUSION**

16 For the reasons set forth above, KFx's motion should be denied.

17 Dated: June 29, 2012

18 By: /s/ Salvatore P. Tamburo

19
20
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CERTIFICATE OF SERVICE

I hereby certify that on June 29, 2012, DEFENDANT ARTHREX, INC.'S OPPOSITION
**TO PLAINTIFF'S MOTION TO (A) DISMISS DEFENDANT'S COUNTERCLAIM FOR
INEQUITABLE CONDUCT IN CONNECTION WITH U.S. PATENTS 8,100,942 AND
8,109,969; (B) STRIKE THE CORRESPONDING AFFIRMATIVE DEFENSE; AND (C)
EXTEND TIME TO ANSWER REMAINING COUNTERCLAIM ALLEGATIONS**
electronically filed with the Clerk of the Court using the CM/ECF system, which will send
notification of such filing to the following counsel of record.

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